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## CLAIMS:

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- 1. An *in vitro* method for detecting a cancer-associated marker protein present in a bodily fluid of a mammal which method comprises the steps of:
  - (a) contacting a sample of bodily fluid from said mammal with antibodies directed against at least one epitope of said marker protein; and
  - (b) detecting the presence of any complexes formed between said antibodies and any marker protein present in said sample;

wherein said antibodies are mammalian autoantibodies to said cancer-associated marker protein which are derived from the same species as the mammal from which said sample has been obtained.

- 2. A method as claimed in claim 1 wherein said sample is from a mammal substantially asymptomatic for pre-neoplasia or cancer.
- 3. A method as claimed in claim 1 wherein said sample is from a mammal symptomatic for cancer.
- A method as claimed in claim 1 wherein said sample is from a mammal which has received therapy
   for cancer.
  - 5. A method as claimed in any preceding claim wherein the mammal is a human and the autoantibodies are human autoantibodies.
    - 6. A method as claimed in any preceding claim

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wherein said bodily fluid is plasma, serum, whole blood, urine, faeces, lymph, cerebrospinal fluid or nipple aspirate.

- 7. A method as claimed in any preceding claim wherein said cancer-associated marker protein is associated with lymphomas, leukaemias, breast cancers, colorectal cancers, lung cancers, pancreatic cancers, prostate cancers, cervical cancers, ovarian cancers, endometrial cancers or cancers of the skin.
  - 8. A method as claimed in claim 7 wherein said cancer-associated marker protein is a breast cancer-associated marker protein.
  - 9. A method as claimed in any preceding claim wherein said cancer-associated marker protein is a modified MUC1, BRCA1, p53, c-myc c-erb $\beta$ 2 or Ras protein.
  - 10. A method as claimed in claim 8 wherein said cancer-associated marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erb $\beta$ 2 or Ras protein associated with primary breast cancer.
  - 11. A method as claimed in claim 8 wherein said cancer-associated marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erb $\beta$ 2 or Ras protein associated with advanced breast cancer.
  - 12. A method as claimed in claim 10 wherein said autoantibodies are obtainable from monocytes isolated from a patient with primary breast cancer.
- 35 13. A method as claimed in claim 11 wherein said autoantibodies are obtainable from monocytes isolated from a patient with advanced breast cancer.

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- 14. A method as claimed in any preceding claim wherein said autoantibodies are produced by an immortalized cell or cell population.
- 5 15. A method as claimed in any one of claims 1 to 14 wherein said autoantibodies are polyclonal antibodies.
- 16. A method as claimed in any preceding claim
  wherein said autoantibodies are immobilized on a
  solid surface.
  - 17. A method as claimed in claim 16 wherein any complexes formed between said autoantibodies and any cancer-associated marker protein present in said sample are detected using secondary antibodies or autoantibodies specific for at least one epitope of said marker protein, said secondary autoantibodies carrying a detectable label.
  - 18. A method as claimed in claim 16 wherein in addition to said sample a labelled cancer-associated marker protein is added carrying at least one epitope recognised by said autoantibodies.
  - 19. Use of a method as claimed in any one of claims 1 to 18 to screen for recurrence of cancer after a treatment, to monitor systemic therapies or to select therapies.
  - 20. A diagnostic reagent which comprises mammalian autoantibodies with a specificity for at least one epitope of a mammalian cancer-associated marker protein.
  - 21. A diagnostic reagent as claimed in claim 20 for use in detecting the presence of a mammalian

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cancer-associated marker protein in a sample of body fluid.

- 22. A reagent as claimed in claim 20 or claim
  5 21 wherein said autoantibodies are human
  autoantibodies and said marker protein is a human
  cancer-associated marker protein.
- 23. A reagent as claimed in any one of claims
  21 or 22 wherein said autoantibodies have specificity
  for at least one epitope of a cancer-associated
  marker protein associated with lymphomas, leukaemias,
  breast cancers, colorectal cancers, lung cancers,
  pancreatic cancers, prostate cancers, cervical
  cancers, ovarian cancers, endometrial cancers or
  cancers of the skin.
  - 24. A reagent as claimed in claim 23 wherein said autoantibodies have specificity for at least one epitope of a breast cancer-associated marker protein.
  - 25. A reagent as claimed in any one of claims 20 to 24 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erb $\beta$ 2 or Ras protein.
  - 26. A reagent as claimed in claim 24 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erbβ2 or Ras protein associated with primary breast cancer.
  - 27. A reagent as claimed in claim 24 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erbβ2 or Ras protein associated with advanced breast cancer.
    - 28. A reagent as claimed in claim 26 wherein

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said autoantibodies are obtainable from monocytes isolated from a patient with primary breast cancer.

- 29. A reagent as claimed in claim 27 wherein said autoantibodies are obtainable from monocytes isolated from a patient with advanced breast cancer.
- 30. An immortalized cell population capable of producing autoantibodies directed against at least one epitope of a mammalian cancer-associated marker protein.
- 31. An immortalized cell population as claimed in claim 30 which is capable of producing autoantibodies directed against at least one epitope of a human cancer-associated marker protein.
- 32. An immortalized cell population as claimed in claim 31 or claim 32 wherein said autoantibodies are directed against at least one epitope of a cancer-associated marker protein associated with lymphomas, leukaemias, breast cancers, colorectal cancers, lung cancer, pancreatic cancers, prostate cancers, cervical cancers, ovarian cancers, endometrial cancers or cancers of the skin.
- 33. An immortalised cell population as claimed in claim 32 wherein said autoantibodies are directed against an epitope of a breast cancer-associated marker protein.
- 34. An immortalized cell population as claimed in any one of claims 31 to 33 wherein said autoantibodies are directed against a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erbβ2 or Ras protein.
  - 35. An immortalized cell population as claimed

in claim 33 wherein said autoantibodies are autoantibodies to a modified MUC1, BRCA1, BRCA2, c-myc, p53, c-erb $\beta$ 2 or Ras protein associated with primary breast cancer.

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- 36. An immortalized cell population as claimed in claim 33 wherein said autoantibodies are autoantibodies to a modified MUC1, BRCA1, BRCA2, c-myc, c-erb $\beta$ 2 or Ras protein associated with advanced breast cancer.
- 37. An immortalized cell population as claimed in anyone of claims 30 to 36 which is derived from monocytes isolated from a patient or a group of patients having cancer or other neoplasia.
- 38. An immortalised cell population as claimed in claim 35 wherein said cell population is derived from monocytes of a patient or group of patients having primary breast cancer.
- 39. An immortalised cell population as claimed in claim 36 wherein said cell population is derived from monocytes of a patient or group of patients with advanced breast cancer.
- 40. A kit for detecting a cancer-associated marker protein present in a bodily fluid of a mammal, the kit comprising:

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(a) mammalian autoantibodies directed against a cancer-associated marker protein from the same species as said autoantibodies; and

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(b) means for detecting the formation of complexes between said autoantibodies and said cancer-associated marker protein.

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- 41. A kit as claimed in claim 40 wherein said autoantibodies are human autoantibodies
- 42. A kit as claimed in claim 40 or 41 wherein said autoantibodies are human autoantibodies.
  - 43. A kit as claimed in any one of claims 40 to 42 wherein said marker protein is a cancer-associated marker protein associated with lymphomas, leukaemias, breast cancers, colorectal cancers, lung cancers, pancreatic cancers, prostate cancers, cervical cancers, ovarian cancers, endometrial cancers or cancers of the skin.
- 15 44. A kit as claimed in claim 43 wherein said marker protein is a breast-cancer associated marker protein.
  - 45. A kit as claimed in any one of claims 40 to 44 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erbβ2 or Ras protein.
- 46. A kit as claimed in claim 45 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, c25 myc, p53, c-erbβ2 or Ras protein associated with primary breast cancer.
- 47. A kit as claimed in claim 45 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, p53,
   30 c-myc, c-erbβ2 or Ras protein associated with advanced breast cancer.
- 48. A method for detecting a cancer-associated marker protein present in a bodily fluid of a mammal substantially as described herein with reference to the accompanying examples.

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49. A kit for detecting a cancer-associated marker protein present in a bodily fluid of a mammal substantially as described herein with reference to the accompanying examples.

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50. A diagnostic reagent substantially as described herein with reference to the accompanying examples.

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51. An immortalized cell population capable of producing autoantibodies directed against one or more epitopes of a cancer-associated marker protein substantially as described herein with reference to the accompanying examples.

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